69. The method as set forth in claim 66, wherein the first and third layers are formed from a non-woven, perforated, non-adherent high density polyethylene material.

70. The method as set forth in claim 69, wherein the second layer is formed from a non-woven, absorbent rayon/polyester material.

71. The method as set forth in claim 49, wherein the dressing is fixed in place with an occlusive or semi-occlusive layer which maintains the dressing in a moist condition.

72. The method as set forth in claim 71, wherein the occlusive or semi-occlusive layer is an adhesive film. --

REMARKS

No new matter has been added in the claims, and entry of these amendments is respectfully requested.

New claims 27 - 49 have been revised as set out below to meet the rejections under 35 USC 112, second paragraph. Previous claims 4 and 22 have now re-ordered so as not to refer to later claim, as noted in the Office Action. Original claim 5, now claims 30 and 52, have been amended to clarify that the slit, which is formed from the edge of the dressing which is parallel to the fold line, is generally perpendicular to the fold line, as supported by the original figures and specification.

The specification has been amended at page 2 to address the errors noted by the Examiner. Page 4 has been amended to correct the reference numerals 36, 38, 40 and 42 to be 38, 40, 42 and 44 respectively, to accord to the rest of the specification and the original figures.

Finally, in the formal drawings, Figures 4 and 5 have been revised to switch the reference numerals 20 and 22 to accord to the specification and the other figures. The formal drawings remove the black shading objected to in the informal drawings. Figure 2, objected to as not showing item 36, is now correct, in that page 8 of the specification now correctly refers to reference numeral 38, shown in Figure 2.

Applicants appreciate the Examiner's assistance in locating these errors in the specification and figures.

I. <u>Claim Rejection – 35 USC § 112, second paragraph:</u>

The Office Action includes a rejection of claims 3 - 22, 25 and 26 under 35 USC 112, second paragraph, in that these claims refer to "The dressing or method." In the new claims,

independent claims 27 and 49 generally conform to original claims 1 and 2 directed to a dressing and a method respectively. However, original dependent claims 3 - 24 (now claims 26 - 48 and 50 - 72) have been amended and renumbered to avoid referring both a dressing or a method of claims 1 and 2. New claims 28-48 generally conform to original claims 3-22, 25 and 26 but are addressed to solely a "dressing" instead of a "dressing or method". New claims 50-70 generally conform to original claims 3-22, 25 and 26 but are addressed to solely a "method" instead of a "dressing or method". This revision is believed to overcome this 112 rejection. As well, previous amendments to claims 4 and 22, not entered from Applicants' previous amendment, are included in the new claims, but with revised claim ordering so as not to refer to a later claim.

The Office Action also rejected claims 21 and 26, under section 112, second paragraph, stating that the term"the optional third layer" lacks antecedent basis. In the new claims, the term "optional" is removed from the phrase "optional third layer" in claims 46, 47, 68 and 69.

II. <u>Claim Rejections – 35 USC § 103(a):</u>

A) Claims 1-22, 25 and 26 are rejected under 35 USC § 103(a) as being unpatentable over WO 98/41095 (hereinafter Burrell et al.) in view of US Patent No. 3,918,446 (hereinafter Buttaravoli). The Office Action states, in respect of Burrell et al.:

> As regards claim 1, Burrell et al., disclose substantially all features of the claimed invention including a multi-layer laminated wound dressing (Fig. 2). The dressing includes first (12), second (14) and third (16) layers, wherein the first and third layers are constructed from perforated, non-adherent materials which carry an anti-microbial coating on one or more surfaces (page 12, lines 28-29). The second layer is sandwiched between the first and third layers and is formed from an absorbent material. Burrell et al. fail to teach top and bottom dressings and a slit in the bottom dressing.
>
> In respect of the Buttaravoli patent the Office Action states:
>
> Buttaravoli discloses a securement device for an intravenous catheter(transcutaneous medical device) and its tubing. Buttaravoli's device comprises an upper and a bottom pad having at least one slit.
>
> The Office Action further states:
>
> It would have been obvious to one having ordinary skill in the art to modify Burrell et al. to include an additional dressing having a slit therein in order to provide the user with a securement device for an intravenous catheter having anti-microbial effects.

Applicants respectfully disagree with this rejection under section 103. Applicants submit that there is not a proper *prima facie* case for obviousness in that is no suggestion to combine

5

these references found within the references themselves. Furthermore, even if combination of these references is valid, which the Applicants refute, Applicants respectfully submit that such combination would still not render obvious the invention as claimed herein.

Firstly, it is worthwhile to review the language of the broad independent claims of this application, now claims 27 and 49. These claims are set out below, with underlining being added to emphasize the features not found in the Burrell et al. reference, which is not directed to a transcutaneous device dressing, and the Buttaravoli reference, which is directed to a very particular type of a transcutaneous device dressing:

27. A transcutaneous device dressing for use with a transcutaneous medical device which has punctured the skin of a patient and which has a portion of the medical device protruding from the skin, comprising:

a top and a bottom dressing, both being formed from a flexible material and having upper and lower surfaces, the lower surfaces being skin facing when the dressing in use;

the bottom dressing having a slit formed therein extending from one edge inwardly to a termination point within the confines of the bottom dressing;

an anti-microbial material provided without the use of adhesives at the upper and lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

whereby, in use, the bottom dressing is placed next to the skin, the slit allowing the bottom dressing to surround the puncture site such that the lower surface of the bottom dressing is in contact with the skin and the upper surface of the bottom dressing is in contact with a portion of the medical device protruding from the skin, and the top dressing is placed above the puncture site such that its lower surface is in contact with a portion of the medical device protruding from the skin, thereby exposing a portion of the medical device protruding from the skin from above and below to the anti-microbial activity of the anti-microbial material.

49. A method of dressing the puncture site of a transcutaneous medical device to limit infection by microorganisms from the surrounding skin and a portion of the medical device that protrudes from the skin of a patient, comprising:

providing a transcutaneous device dressing, comprising:

a top and a bottom dressing, both being formed from a flexible material and having upper and lower surfaces, the lower surfaces being skin facing when the dressing is in use;

the bottom dressing having a slit formed therein extending from one edge inwardly to a termination point within the confines of the bottom dressing; and

an anti-microbial material provided without the use of adhesives at the upper and lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

sliding the bottom dressing in place next to the skin using the slit to allow the bottom dressing to surround the puncture site at the termination point such that the lower surface of the bottom dressing is in contact with the skin surrounding the puncture site and the upper surface of the bottom dressing is in contact with a portion of the medical device protruding from the skin;

applying the top dressing above the bottom dressing such that the lower surface of the top dressing is in contact with a portion of the medical device protruding from the skin;

6

depending on the anti-microbial material, applying a water or alcohol based electrolyte to the dressing to release the anti-microbial material; and

fixing the top and bottom dressings to the skin.

Thus, the present application claims a "transcutaneous device dressing for use with a transcutaneous medical device which has punctured the skin of a patient and which has a portion of the medical device protruding from the skin". Such dressings are often termed "catheter patches" for short, which terminology is sometimes used herein after, without intending to limit the dressing usages to only catheters. In contrast, the cited Burrell et al. reference teaches a multi-layer laminated wound dressing, with no mention whatsoever of a catheter patch or a method of using/modifying the dressing to address the particular infection problems associated with a catheter patch. Thus, Burrell et al., is not itself suggestive of any modification relating to catheter patches. Buttaravoli teaches a securement device for an intravenous catheter that uses adhesives for securing the dressing to the skin, and for securing the top dressing to the bottom dressing. Furthermore, the antimicrobial activity is only provided in the Buttaravoli reference as part of the adhesives. As pointed out in the Background section of the instant application, this approach does fully address an infection problem that exists below the catheter when sitting on the bottom layer of a dressing. In Buttaravoli, in viewing Figures 3 and 4 (embodiment 1), or Figure12 (embodiment 2), the area beneath the catheter as it rests on the bottom layer receives no anti-microbial treatment, and as such there may still be a substantial possibility of catheter related infections. Only the bottom of the lower dressing and the downwardly facing part of the top dressing have anti-microbial material provided through the adhesives.

The serious shortcomings of the Buttaravoli patent are addressed by the Applicants at page 2, lines 14 - 22 of the instant application:

> This device [Buttaravoli's] has the disadvantage of using adhesives with the antibacterial agent, which limits the effectiveness and long lasting ability of the antibacterial agent. Furthermore, the adhesive can be irritating next to the skin, cause skin damage and patient discomfort on removal, and inhibits the removal or changing of the device. Furthermore, many adhesives act as moisture barriers, which can limit the effectiveness of the antibacterial agent. Finally, the device of this patent teaches including a slit in the bottom pad of the dressing, which lies below the intravenous needle or catheter when the device is in place, allowing the intravenous device to remain in contact with the skin, and therefore limiting the infection control of the device.

The last point (infection through the slit) in respect of the Buttaravoli patent is best seen with reference to Figures 9 - 12, showing two slits in the bottom dressing parallel to catheter device, one of which must lie beneath the catheter device in Figure 12, thus exposing the catheter device to the skin through the unused slit. This is an important disadvantage to the infection control afforded by the Buttaravoli device. In contrast, claims 30 and 52 of Applicant's application has a preferred orientation of the catheter perpendicular to the direction of the slit, thereby avoiding catheter contact with the skin and also catheter motion along the length of the slit. The parallel slit orientation of Buttaravoli substantially increases the probability of infection. When the catheter is parallel to the slit any movement of the dressing will result in increased contact between the catheter and the skin through the slit. It is important to note that the catheter barrel itself is the principal route of catheter-related infection. A patient implanted with a transcutaneous medical device perspires creating a moist area on the skin beneath the catheter causing the catheter barrel to comprise a channel for microbial infection and migration. When the underside of the catheter is not protected against microbial attack, or when the area under the slit is not protected against microbial attack, the chances of infection are heightened. Applicant's device of claim 30 and 52 results in the catheter being perpendicular to the slit, which minimizes contact of the catheter barrel with the skin. Furthermore, as emphasized above, Applicant's claim 27 and 49 places anti-microbial material such that it is released both above and below the protruding medical device. Thus, the device of present application isolates the catheter from the skin with an anti-microbial barrier that is both above and below on both sides of catheter.

Applicants emphasize the distinguishing claim language over the prior art. Firstly (using the claim language of independent claims 27 and 49) by "an antimicrobial material provided without the use of adhesives at the upper and lower surfaces of the bottom dressing" thus "exposing a portion of the medical device protruding from the skin from above and below to the anti-microbial activity of the anti-microbial material". Secondly, using the revised claim language of claims 30 and 52, "the slit is formed from the edge of the bottom dressing which is parallel to the fold line, such that the slit is generally perpendicular to the fold line". This second feature, the perpendicular arrangement of the slit is opposite to that used by Buttaravoli, limiting

the chance of infection with any portion of the slit being parallel to the catheter device, allowing the catheter device to contact the skin through the slit.

As set out above, Applicants respectfully submit that there is no proper *prima facie* case of obviousness, since the references themselves are not suggestive of the combination of features as suggested by the Examiner. For references to be combined in a proper 103 rejection, the suggestion to combine must come from the references themselves. As *Al-Site Corp.* v. *VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161(Fed. Cir. 1999)., points out: "Obviousness is not to be determined in hindsight of Applicant's invention". The mere fact that the prior art could be modified (substantial modification being required for both Burrell and Buttaravoli to result in the present application) would not have made the modification obvious unless the prior art suggested the desirability of the modification (*In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). With Buttaravoli the modifications that would be required would destroy the intended function of his device, and in fact discard most of the device features altogether. Buttaravoli would have to be modified in a manner to drop his adhesives, his antimicrobial agent placement in those adhesives, add antimicrobial agents to both the top and bottom layers of the bottom dressing, drop the complicated hinged flap arrangement of his first embodiment, drop the strips protecting the adhesives, drop the extra slits, and change the orientation of the slits. There is certainly no suggestion to do that within the Buttaravoli patent. Similarly, there is no suggestion to make those modifications coming from the Burrell et al. reference, since Burrell et al. is not directed to a catheter patch or its peculiar infection problems.

Buttaravoli's only approach is antimicrobial adhesives in a catheter patch. This leaves a major problem of protecting catheter laying on the bottom dressing which is not in contact with anti-microbial material. *In re Napier*, 55F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995) the court held that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. With Buttaravoli, it was believed that the problem of catheter-related infections is solved, albeit poorly, by using anti-microbial material in the adhesives.

Just because the present application provides a solution that is simple does not mean that the solution is obvious. As *In re Dance,* 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998)., points out: the prior art items themselves must suggest the desirability and thus the

5

obviousness of making the combination without the slightest recourse to the teachings of the patent or application. Neither Burrell et al., nor Buttaravoli suggests the desirability of making the combination suggested in the Office Action. It is believed that only the claims of the present invention can be seen to motivate the combination, which is clearly not a proper basis for a *prima facie* case of obviousness.

Reconsideration of the rejection under 103 against both of the independent claims 27 and 49 is respectfully requested. The Office Action includes a number of other rejections under 103 directed at each of the dependent claims. It is Applicants' respectful submission that the dependent claims are all unobvious both by virtue of the unobviousness found in the independent claims, and because the references themselves do not suggest the combinations of the features found in the dependent claims. Thus Applicants have not addressed each of these rejections individually. However, certain of the comments made in the Office Action in respect of the dependent claims are particularly incorrect, and thus Applicants have commented on these below. As *Hybritech, Inc.,* v. *Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1383, 231 USPQ 81, 93(Fed. Cir. 1986) points out, obviousness is based on the claimed invention as a *whole* relative to the prior art and one should not look to the obviousness of substitutions and differences of the claimed invention from the prior art. Also, *Kimberly-Clark Corp.* v. *Johnson & Johnson,* 745 F.2d 1437, 1448, 223 USPQ 603, 609-610 (Fed Cir. 1984), indicates that it is immaterial to the issue that all elements were old in other contexts. What must be found obvious to defeat the application is the claimed combination. Burrell et al. makes no suggestion of modifying its dressing in any direction such as with transcutaneous devices. Modifying Buttaravoli in view of Burrell et al. to attempt to create the claimed invention discards virtually the entire device of Buttaravoli. Such combination would be improper as it would require a substantial reconstruction and redesign of the elements shown in the prior art references (*In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959)).

The Office Action indicates, in respect of original claim 2, now claim 49, that the modified device of Burrell et al. is placed on a user in a manner similar to that of Buttaravoli. Applicants respectfully disagree. Buttaravoli employs adhesives to affix the bottom dressing to the skin, and to join the upper and lower dressing pads, and within these adhesives is the anti-microbial material. In the present application "an anti-microbial material [is] provided without

the use of adhesives..." and the "anti-microbial material [is] provided...at the upper and lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing." Buttaravoli also does not provide anti-microbial activity to the underside of the protruding catheter laying on the bottom dressing as such is not in contact with the anti-microbial material in the adhesives (Fig. 3, 4 and 12 of Buttaravoli). The language of claim 49 clearly distinguishes, in that the anti-microbial material is provided at the upper surface of the bottom dressing and "the upper surface of the bottom dressing is in contact with a portion of the medical device protruding from the skin". Claim 49 also indicates, "depending on the anti-microbial material, applying a water or alcohol based electrolyte to the dressing ... release[s] the anti-microbial material". Buttaravoli has no equivalent 'anti-microbial activity release mechanism'.

The Office Action rejects claim 4 in that the abstract, and page 9, line 22-page 11, line 10 and page 12 lines 28-29 (presumably of Burrell et al.) disclose that the anti-microbial material is deposited on one or more surfaces of the substrate. Applicants respectfully submit that the Burrell et al. reference does not relate to a catheter patch, and thus has no equivalent of a top and bottom dressing, with antimicrobial coatings on multiple of its surfaces.

The Office Action rejects claim 5 in that Fig. 9 of Buttaravoli shows a fold line (66) that is parallel to the slit(76). Applicants have revised this claim (now claims 30 and 52), and respectfully submit that the Office Action misinterprets the original claim. Claims 30 and 52 now clarify that the slit that is perpendicular to the fold line in that "the slit is formed from the edge of the bottom dressing which is parallel to the fold line"(Emphasis added). This is an important distinction from Buttaravoli, which has a slit parallel to the fold line, and thus parallel to the catheter device. Buttaravoli thus increases the chance of infection through the slit, while Applicants' perpendicular arrangement minimizes infection (see Figures of instant application).

The Office Action rejects claim 7, stating that Fig. 2 and page 16, lines 5-21 of Burrell et al. discloses the dressing is constructed from first second and third layers, and when modified to include two dressings as disclosed in Buttaravoli, both the top and bottom dressings will include three layers. Applicants respectfully traverse this rejection for the reasons set out above. There is no suggestion to modify Buttaravoli to use the superior antimicrobial dressing materials disclosed by Burrell et al., when Buttaravoli uses antimicrobial adhesives, and when Burrell et al., is directed only to a wound dressing material.

5

The Office Action rejects claims 10 and 11, noting that page 3, lines 9-19 of Burrell et al. Since Burrell et al. is not directed to a catheter patch, Applicants respectfully submit that there is no direction that the "top and bottom dressings are sized so as to provide coverage of the portion of the medical device protruding from the skin of at least about 5 mm"(Emphasis added).

B) The Office Action rejects claims 23 and 24 (now claims 71 and 72) under 35 USC § 103(a) as being unpatentable over Burrell et al. in view of Buttaravoli, as applied to claims 2 and 22 respectively, and in further view of US Patent 4,738,257 (Meyer et al.). The Office Action states with respect to the Meyer et al. patent:

> As regards both claims 23 and 24, both Burrell et al. and Buttaravoli fail to teach an occlusive or semi-occlusive layer which maintains the dressing in moist condition. However, Meyer et al. teach a dressing fixed in place with occlusive film layer in order to maintain the dressing in a moist condition. It would have been obvious to one having ordinary skill in the art to provide the modified device of Burrell et al. with an occlusive film layer in order to maintain moisture in the dressings, as suggested by Meyer et al.

Applicants respectfully disagree. The rejected claims relate to the Applicants' dressing being fixed in place with an occlusive or semi-occlusive layer which maintains the dressing in a moist condition (claim 71), and the occlusive or semi-occlusive layer being an adhesive film (claim 72). Buttaravoli's use of antimicrobial adhesives is opposite to any need for an occlusive or semi-occlusive layer which maintains the dressing in moist condition. Moisture is likely to interfere with the adhesives within Buttaravoli's device. Thus, to suggest modifying Buttaravoli in this manner modifies in a direction opposite to the reference, and in a direction which would destroy the reference device. Hence such combination of references is submitted to be improper. There is no need to add an occlusive or semi-occlusive layer to Buttaravoli. In the instant claimed invention, maintaining a moist condition is for the release of anti-microbial material. Buttaravoli has no such 'anti-microbial activity release mechanism' and as such would have no need for an occlusive or semi-occlusive layer. Burrell teaches a wound dressing but makes no suggestion of how to make or use a transcutaneous device dressing. Meyers et al. is not a catheter patch patent at all, nor does it include an anti-microbial coating which is released with moisture, so there is no suggestion within the art itself to warrant the combination of references.

[redacted]ctfully submits that for there to be a proper 103 rejection the prior art [redacted]uggest the desirability and thus the obviousness of making the

combination without the slightest recourse to the teachings of the patent or application (*In re Dance)*. For these reasons, reversal of this 103 rejection is respectfully requested.

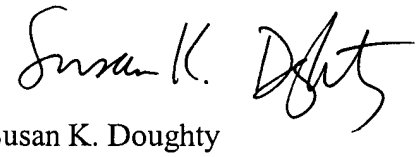
Conclusion

Support for the amendments is found throughout the specification and claims as originally filed. No new matter is believed to have been introduced, and entry of these amendments is respectfully requested.

The amended claims are believed to be definite and satisfy the requirements of 35 U.S.C.103 and 112. Accordingly, reconsideration and allowance of the subject application are respectfully requested.

This response is accompanied by a check in the amount of $1,064 for a three month extension of time ($920) and eight dependent claims ($144). Applicants note that in response to Missing Parts, 38 total claims were paid for. This response contains 46 claims, thus giving a difference of eight claims. If the enclosed amount submitted is incorrect, please deduct any deficiency or credit any overpayment to deposit account no. 07-1969.

Respectfully submitted,



Susan K. Doughty
Reg. No. 43,595

GREENLEE, WINNER & SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone: (303) 499-8080
Facsimile: (303) 499-8089
Email: winner@greenwin.com
Attorney docket No. 30-00
SKD:lla:5/24/02

PAGE 2, LINES 9 - 22:

A securement device[s] is taught for securing [a] an intravenous device to the body in US Patent 3,918,446, issued November 11, 1975 to Buttaravoli. The device has an upper and a lower pad, between which the intravenous device is fixed. Since the function of the device is to secure the device to the body, there is a teaching to provide an adhesive material to the bottom of lower pad, and to the bottom of the top pad. There is a mention of providing the adhesive with an antibacterial agent. This device has the disadvantage of using adhesives with the antibacterial agent, which limits the effectiveness and long lasting ability of the antibacterial agent. Furthermore, the adhesive can be irritating next to the skin, cause skin damage and patient discomfort on removal, and inhibits the removal or changing of the device. Furthermore, many adhesives act as moisture barriers, which can limit the effectiveness of the antibacterial agent. Finally, the device of this patent teaches including a slit in the bottom pad of the dressing, which lies below the intravenous needle or catheter when the device is in place, allowing the intravenous device to remain in contact with the skin, and therefore limiting the infection control of the device.

PAGE 8, LINES 3 - 13:

Figure 4, 5, and 6 demonstrate placement of the dressing 10 around a catheter 32, with the bottom dressing 22 sliding under the catheter 32 such that the lower surface [36] 38 (see Figure 2) of the bottom dressing 22 contacts the patient's skin (not shown), while the upper surface [38] 40 of the bottom dressing 22 contacts the catheter 32 protruding from the skin. Once the top dressing 20 is applied, by folding it over the bottom dressing 22, the lower surface [40] 42 (see Figure 2) of the top dressing 20 is in contact with the catheter 32 protruding from the skin. The upper surface [42] 44 of the top dressing 20 is then covered with the occlusive or semi-occlusive layer 36, as shown in Figure 3. As shown in Figures 4 and 5, when the dressing

10 is formed from a unitary dressing, the lower surface[40] 42 of the top dressing 20 and the upper surface 40 of the bottom dressing 22, are one and the same layer, represented as layer 16 in Figure 1.

6